Translation

050205

PCT/JP2003/008020

PATENT COOPERATION TREATY

PCT

10/511098

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SK245WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/008020	International filing date (*day/month/year*) 25 June 2003 (25.06.2003)	Priority date (*day/month/year*) 25 June 2002 (25.06.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/09, C07K 16/42, 19/00, C12N 1/21, C12P 21/02, C12N 9/90 // (C12N 1/21, C12R 1:19), (C12P 21/02, C12R 1:19)		
Applicant SEKISUI CHEMICAL CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26 December 2003 (26.12.2003)	03 September 2004 (03.09.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/008020

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-37, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 33-64, filed with the letter of 17 June 2004 (17.06.2004)

☒ the drawings:

pages 1-5, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:

pages 1-21, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☒ the claims, Nos. 1-32
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/08020

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	33-64	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	33-64	NO
Industrial applicability (IA)	Claims	33-64	YES
	Claims		NO

2. Citations and explanations

Document 1: WO, 00-075346, A1 (Medical Research Council), 14 December, 2000 (14.12.00)
Document 2: (A. Ideno, et al.), Eur J Biochem, 2000, Vol. 267 (11), pages 3139-3149
Document 3: (S. Behrens, et al.), EMBO J, 2001, Vol. 20 (1-2), pages 285-294
Document 4: (T. Maruyama, et al.), Front Biosci, 2000, Vol. 5, pages D821-836
Document 5: (G. C. Huang, et al.), Protein Sci, 2000, Vol. 9 (6), pages 1254-1261
Document 6: (T. Zarnt, et al.), J Mol Biol, 1997, Vol. 271 (5), pages 827-837
Document 7: (J. P. Arie, et al.), Mol Microbiol, 2001, Vol. 39 (1), pages 199-210
Document 8: (T. Ratajczak, et al.), J Biol Chem, 1993, Vol. 268 (18), pages 13187-13192
Document 9: (F. Pirkl, et al.), J Mol Biol, 2001, Vol. 308 (4), pages 795-806
Document 10: (K. Ramm, et al.), J Biol Chem, 2000, Vol. 275 (22), pages 17106-17113

Claims 33-64

The subject matters of claims 33-64 do not appear to involve an inventive step in view of documents 1-10.

Document 1 describes (1) (a) a first nucleic acid sequence to code for a fragment of a chaperon polypeptide that is bound to a promoter capable of expressing the first nucleic acid sequence in a manner that they can operate and (b) an expression vector containing a cloning site to enable the insertion of a second nucleic acid sequence in a manner that the second nucleic acid sequence is bound to the said first nucleic acid sequence and expressed as fused with the said first nucleic acid sequence, (2) a feature wherein a linker region that can be cleaved is further contained between the first and second regions, (3) a feature wherein a typical such linker is a polypeptide chain that can be cleaved by a protease or other means suitable for cleaving polypeptides, (4) a feature wherein the chaperon fragment is disposed at the N-terminal of a desired polypeptide of the fused protein, (5) a feature wherein the said vector is advantageous for preparing proteins such as antibodies and endogenous membrane proteins, and (6) a feature wherein *Escherichia coli* can also be used as host cells.

Document 2 describes PPIase of FKBP type derived from archaebacteria; document 3 describes SurA-type PPIase of parvulin-type; document 4 contains a general discussion on PPIase derived from archaebacteria, and describes FKBP-type PPIase, parvulin-type PPIase and cyclophilin-type PPIase; document 5 describes FKBP-type PPIase of trigger-factor type; document 6 describes that N-terminal and C-terminal fragments of PPIase of trigger-factor type are contained; documents 7 and 10 describe PPIase of FkpA type; document 8 describes PPIase of FKBP52 type, and document 9 describes PPIase of Cyp40 type.

There would be no difficulty in applying, as the chaperon fragment in the vector described in document 1, PPIases that were well known as molecules having a chaperon activity prior to the filing of the present application, as described in documents 2-10, or choosing such specific PPIase as described in documents 2-10 as the above-mentioned PPIases.